

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

KATHRYN M. NELSON,

Plaintiff,

AFFINITY HEALTH SYSTEM, NETWORK HEALTH PLAN,

Involuntary Plaintiff,

CASE NO: 12-CV-00472

v.

JOHNSON & JOHNSON,
ETHICON, INC., GYNECARE WORLDWIDE,
ETHICON WOMAN'S HEALTH AND UROLOGY,
JOHN DOE CORPORATIONS 1-50

Defendants

COMPLAINT

The above-named plaintiff, Kathryn Nelson, by HABUSH HABUSH & ROTTIER S.C., her attorneys, as and for a Complaint against the above-named defendants, alleges and show to the Court as follows:

1 Plaintiff, Kathryn Nelson, brings this case against Defendants for the injuries arising from the implantation into Ms. Nelson of Pelvic Mesh Products that were negligently manufactured and designed by the Defendants and failed to contain appropriate and significant warnings relating to their use.

PARTIES

2. Plaintiff, Kathryn Nelson, resides, and at all times material hereto has resided, at 1025 E. Tennessee Ave., in the City of Oshkosh, Winnebago County, Wisconsin.

3. Involuntary plaintiff, Affinity Health System, Network Health Plan is a Wisconsin health insurance plan organized and existing under and by virtue of the laws of the State of Wisconsin, with offices located at 1570 Midway Place, Menasha, WI 54952; this insurance carrier is an involuntary plaintiff by reason of Wis. Stat. §803.03, as it may have an interest in the plaintiff's claim by reason of its being the medical insurance carrier for the plaintiff, Kathryn Nelson.

4. Defendant Johnson & Johnson ("Johnson & Johnson") is a New Jersey Corporation. At all times material, Johnson & Johnson did business in the State of Wisconsin.

5. Defendant Ethicon, Inc. is a New Jersey Corporation. Ethicon, Inc. is a subsidiary of Johnson & Johnson. At all times material, Ethicon, Inc. did business in the State of Wisconsin.

6. Defendant Gynecare Worldwide ("Gynecare Worldwide") is a division of Ethicon, Inc, a New Jersey Corporation. At all times material, Gynecare Worldwide did business in the State of Wisconsin.

7. Defendant Ethicon Women's Health & Urology ("Ethicon Women's Health") is a division of Ethicon, Inc. At all times material, Ethicon Women's Health & Urology did business in the State of Wisconsin.

JURISDICTION AND VENUE

8. This is an action for damages in excess of \$75,000.00, exclusive of interest, costs and attorneys' fees.

9. At all times material hereto, the parties to this action were residents of different states and, accordingly, this Court has diversity jurisdiction pursuant to 28 U.S.C § 1332.

10. At all times material the plaintiff was a resident of the State of Wisconsin, had her surgery in the State of Wisconsin and the defendants did business in the State of Wisconsin and, therefore, venue is appropriate in the United States District Court for the Eastern District of Wisconsin; this action would properly be classified as a “tag along action” subject to transfer/removal to the United States District Court for the Southern District of West Virginia pursuant to the Order of the Judicial Panel on Multi District Litigation dated February 7, 2012 and Pretrial Order #1 paragraph 2 dated February 29, 2012 by Honorable Judge Joseph R. Goodwin in MDL 2327.

11. All conditions precedent to the maintenance of this action have occurred, have been performed, or have been waived.

FACTUAL BACKGROUND

12. Defendants and John Doe Corporations 1-50 (collectively “Defendants”) at all times material hereto, were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Gyencare Prolift Total Pelvic Floor Repair System and the Gynecare TVT System (also referred to herein as the Defendants’ “Pelvic Mesh Products”).

13. The Gynecare Prolift Total Pelvic Floor Repair System is an implantable medical device designed to treat pelvic organ prolapse (“POP”) and the Gynecare TVT System is an implantable medical device designed to treat Stress Urinary Incontinence (“SUI”) and relieve the discomfort and bladder control issues that accompany SUI.

14. Defendants’ Pelvic Mesh Products contain monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant Plaintiff is biologically incompatible with human tissue

and promotes a negative immune response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendants' collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign organic material from animals. Cross linked collagen is harsh upon the female pelvic tissue. It hardens in the body. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

15. Defendants sought and obtained FDA clearance to market its Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Pelvic Mesh Products.

16. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original). Pelvic Mesh for the treatment of SUI is similarly defective such that any statements made by the FDA with respect to POP devices should have placed Defendants on notice of the defects and hazards associated with their SUI products.

17. The FDA Safety Communication also stated, "*Mesh contraction (shrinkage) is a previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the

published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.” (emphasis in original).

18. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (“ACOG”) and the American Urogynecologic Society (“AUGS”) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

19. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that “[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk.”

20. The injuries of the Plaintiff are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

21. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

22. Specifically, the FDA Safety Communication stated: “it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk.”

23. Contemporaneously with the Safety Communication, the FDA released a publication titled “Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse” (the “White Paper”). In the White Paper, the

FDA noted that the published, peer-reviewed literature demonstrates that “[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh.”

24. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it “has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.” (Emphasis in original).

25. The FDA White Paper further stated that “these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair.”

26. In its White Paper, the FDA advises doctors to, *inter alia*, “[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.”

27. The FDA concludes its White Paper by stating that it “has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse.”

28. Defendants knew or should have known about the Pelvic Mesh Products’ risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

29. Defendants knew or should have known that the Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

30. The scientific evidence shows that the material from which Defendants' Pelvic Mesh Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Pelvic Mesh Products, including the Plaintiff.

31. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the Plaintiff.

32. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Pelvic Mesh Products were unreasonably susceptible to degradation and fragmentation inside the body.

33. The Pelvic Mesh Products were unreasonably susceptible to shrinkage and contraction inside the body.

34. The Pelvic Mesh Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

35. The Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

36. Defendants omitted the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products, and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as safe medical devices when Defendants knew or should have known that the Pelvic Mesh Products were not safe for their intended purposes, and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff, catastrophic injuries.

37. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Pelvic Mesh Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

38. The specific nature of the Pelvic Mesh Products' defects includes, but is not limited to, the following:

- a. the use of polypropylene and collagen material in the Pelvic Mesh Products and the immune reactions that result from such material, causing adverse reactions and injuries;
- b. the design of the Pelvic Mesh Products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
- c. biomechanical issues with the design of the Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

- d. the use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;
- e. the propensity of the Pelvic Mesh Products for “creep,” or to gradually elongate and deform when subject to prolonged tension inside the body;
- f. the inelasticity of the Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and
- g. the propensity of the Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;
- h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;
- i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;
- j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;
- k. the harshness of Cross linked collagen upon the female pelvic tissue, and the hardening of the product in the body;
- l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

39. The Pelvic Mesh Products are also defective due to Defendants' failure to adequately warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

- a. the Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;
- b. the Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;
- c. the Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;
- d. the rate and manner of mesh erosion or extrusion;
- e. The risk of chronic inflammation resulting from the Pelvic Mesh Products;
- f. the risk of chronic infections resulting from the Pelvic Mesh Products;
- g. the risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products;
- h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;
- i. the need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products;
- j. the severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;
- k. the hazards associated with the Pelvic Mesh Products;
- l. the Pelvic Mesh Products' defects described herein;

- m. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products is no more effective than feasible available alternatives;
- n. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;
- o. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products makes future surgical repair more difficult than feasible available alternatives;
- p. use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
- q. removal of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
- r. complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

40. Defendants had underreported information about the propensity of the Pelvic Mesh Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media.

41. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

42. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists.

43. Feasible and suitable alternatives to the Pelvic Mesh Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Pelvic Mesh Products.

44. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained implanting physicians.

45. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Pelvic Mesh Products and the aftercare of patients implanted with the Pelvic Mesh Products.

46. The Pelvic Mesh Products implanted in the Plaintiff were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

47. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Pelvic Mesh Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain.

48. In many cases, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

49. The medical and scientific literature studying the effects of Defendants' mesh products, like that of the product(s) implanted in the Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Pelvic Mesh Products.

50. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

51. At all relevant times herein, Defendants continued to promote the Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

52. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products.

53. Due to defects in design, manufacture, and warnings, the Pelvic Mesh Products implanted into Ms. Nelson were unreasonably dangerous at the time it left Defendants' control.

Plaintiff's Experience and Injuries

54. On May 14, 2009, Ms. Nelson was implanted with a Gynecare Prolift Total Pelvic Floor Repair System and a Gynecare TVT System which were designed, manufactured, packaged, labeled, marketed, and sold by Defendants.

55. The Pelvic Mesh Products were implanted into Ms. Nelson with the intention of treating her POP and SUI, a use for which Defendants marketed and sold these products.

56. At all times, the Defendants' Pelvic Mesh Products that were implanted in Ms. Nelson were used for the purposes that Defendants marketed the Pelvic Mesh Products.

57. After, and as a result of the surgical implant of Defendants' Pelvic Mesh

Products, Ms. Nelson suffered serious bodily injuries, including extreme pain, dyspareunia and other injuries similar to the ones described in the FDA's Public Health Notification of October 20, 2008 and July 13, 2011.

58. These injuries would not have occurred but for the defective nature of the product implanted and/or Defendants' wrongful conduct.

59. As a result of having the Pelvic Mesh Products implanted, Ms. Nelson has experienced significant mental and physical pain and suffering, undergone multiple surgeries and revisionary procedures, and she has sustained permanent injuries.

COUNT I

(Strict Liability – Defective Design or Manufacture)

60. Plaintiff adopts and realleges paragraphs 1 through 59 above as though fully set forth herein.

61. Defendants placed the Pelvic Mesh Products into the stream of commerce with the actual or constructive knowledge that they would be used without inspection for defects.

62. The Pelvic Mesh Products were defective in their manufacture or design in that the foreseeable risks of harm posed by the Pelvic Mesh Products could have been reduced or avoided by the adoption of a reasonable alternative designs by the Defendants and the omission of the alternative designs rendered the Pelvic Mesh Products not reasonably safe.

63. Because of defects in the Pelvic Mesh Products, they are, and at all times material hereto were, unreasonably dangerous.

64. The defective condition of the Pelvic Mesh Products existed at the time that the Pelvic Mesh Products left the control of the Defendants.

65. The Pelvic Mesh Products reached users and consumers, including the plaintiff, without substantial change in the condition in which they were sold.

66. As a direct and proximate result of the defective and unreasonably dangerous Pelvic Mesh Products, Ms. Nelson suffered extreme pain, suffering, disfigurement and disability, mental and emotional anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earning capacity. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff, Kathryn Nelson, respectfully demands that this Honorable Court enter judgment against the Defendants, jointly and severally, for compensatory damages together with recoverable costs and fees associated with this action, and demands trial by jury of all issues raised herein.

COUNT II
(Strict Product Liability – Failure to Warn)

67. Plaintiff adopts and realleges paragraphs 1 through 66 above as though fully set forth herein.

68. The Pelvic Mesh Products implanted in Ms. Nelson were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the products, including, without limitation, those risks outlined in paragraph 39 above and other injuries similar to the ones described in the FDA's Public Health Notification of October 20, 2008 and July 13, 2011.

69. The Pelvic Mesh Products implanted in Ms. Nelson were used for their intended purpose, *i.e.*, the correction of SUI and POP.

70. Ms. Nelson's physicians, including the surgeon who performed the implant of the Pelvic Mesh Products, could not have discovered any defect with the product through the

exercise of reasonable care.

71. Ms. Nelson's physicians, including the surgeon who performed the implant of the Pelvic Mesh Products, did not have substantially the same knowledge that an adequate warning from the manufacturer or a distributor would have communicated.

72. The warnings that were provided by Defendants regarding the Pelvic Mesh Products were ambiguous or were not sufficient, accurate or clear.

73. The Defendants had a continuing duty to warn Ms. Nelson or her doctors of the dangers associated with the Pelvic Mesh Products.

74. The foreseeable risks of harm posed by the Pelvic Mesh Products could have been reduced or avoided by the provision of reasonable warnings by the Defendants, and the omission of these warnings rendered the Pelvic Mesh Products not reasonably safe.

75. Because of defects in the warnings associated with the Pelvic Mesh Products, they are, and at all times material hereto were, unreasonably dangerous.

76. The defective condition of the warnings associated with the Pelvic Mesh Products existed at the time that the Pelvic Mesh Products left the control of the Defendants.

77. The Pelvic Mesh Products reached users and consumers, including the plaintiff, without substantial change in the condition in which they were sold.

78. As a direct and proximate result of the defective and unreasonably dangerous warnings associated with the Pelvic Mesh Products, Ms. Nelson suffered extreme pain, suffering, disfigurement and disability, mental and emotional anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earning capacity. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff, Kathryn Nelson, respectfully demands that this Honorable Court enter judgment against the Defendants, jointly and severally, for compensatory damages together with recoverable costs and fees associated with this action, and demands trial by jury of all issues raised herein.

COUNT III
(Negligence)

79. Plaintiff adopts and realleges paragraphs 1 through 78 above as though fully set forth herein.

80. Defendants owed a duty to Plaintiff and others similarly situated as foreseeable users of the Pelvic Mesh Products to manufacture and sell them so that they would be reasonably safe for their intended use and free from defects.

81. Defendants were negligent in designing, manufacturing, formulating warnings for and selling the Pelvic Mesh Products by, among other things, failing to properly fabricate the Pelvic Mesh Products, failing to adequately test the Pelvic Mesh Products, and failing to conduct adequate quality control procedures for the Pelvic Mesh Products.

82. As a direct and proximate result of the foregoing negligence of Defendants, Ms. Nelson suffered extreme pain, suffering, disfigurement and disability, mental and emotional anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earning capacity. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff, Kathryn Nelson, respectfully demands that this Honorable Court enter judgment against the Defendants, jointly and severally, for compensatory damages together with recoverable costs and fees associated with this action, and demands trial by jury of all issues raised herein.

COUNT IV
(Breach of Warranties)

83. Plaintiff adopts and realleges paragraphs 1 through 82 above as though fully set forth herein.

84. Defendants impliedly warranted to Plaintiff, her treating healthcare providers and all others similarly situated that the Pelvic Mesh Products were reasonably fit for their intended use or purpose and that they were designed, manufactured and sold in accordance with good design, engineering, and industry standards.

85. The Pelvic Mesh Products were defective in their manufacture or design and were, therefore, not fit for their intended use or purpose and were not designed, manufactured, or sold in accordance with good design, engineering, and industry standards.

86. Defendants breached the above warranties in that the Pelvic Mesh Products were defective as set forth above, were not fit for their intended use or purpose and were not designed, manufactured, or sold in accordance with good design, engineering and industry standards.

87. As a direct and proximate result of the foregoing breaches of warranties, Ms. Nelson suffered extreme pain, suffering, disfigurement and disability, mental and emotional anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earning capacity. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff, Kathryn Nelson, respectfully demands that this Honorable Court enter judgment against the Defendants, jointly and severally, for compensatory damages together with recoverable costs and fees associated with this action, and demands trial by jury of all issues raised herein.

COUNT V
(Punitive Damages)

88. Plaintiff adopts and realleges paragraphs 1-87 of this Complaint as though fully set forth herein.

89. Defendants sold their Pelvic Mesh Products to the healthcare providers of the Plaintiff and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Pelvic Mesh Products were reasonably safe for implantation in the female pelvic area.

90. Defendants sold the Pelvic Mesh Products to the Plaintiff's health care providers and other health care providers in the state of implantation and throughout the United States in spite of their knowledge that the Pelvic Mesh Products can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff and numerous other women.

91. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Pelvic Mesh Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Pelvic Mesh Products' designs or the processes by which the Pelvic Mesh Products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Pelvic Mesh Products as safe and effective.

92. Defendants knew the Pelvic Mesh Products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Pelvic Mesh

Products, as well as other severe and personal injuries which were permanent and lasting in nature.

93. Defendants withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of the Pelvic Mesh Products.

94. Defendants knew and intentionally disregarded the fact that the Pelvic Mesh Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

95. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Pelvic Mesh Products.

96. Notwithstanding the foregoing, Defendants continue to aggressively market the Pelvic Mesh Products to consumers, without disclosing the true risks associated with the Pelvic Mesh Products.

97. Defendants knew of the Pelvic Mesh Products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

98. Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of the Pelvic Mesh Products to ensure continued and increased sales of the Pelvic Mesh Products.

99. Defendants' conduct as described herein evidences malice and/or an intentional disregard of the rights of the plaintiff and other similarly situated individuals, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff, Kathryn Nelson, respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally, for punitive damages in an amount determined by the trier of fact, together with recoverable costs and fees associated with this action, and demands trial by jury of all issues raised herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, for:

1. Compensatory damages to Plaintiff for her extreme pain, suffering, disfigurement and disability, mental and emotional anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earning capacity, not only in the past but also in the future;
- 2.. Reasonable attorneys' fees;
3. Recoverable costs and disbursements under the law;
4. Punitive damages; and
5. Such other and further relief as this Court deems just and proper.

**THE PLAINTIFF DEMANDS TRIAL BY JURY OF ALL ISSUES TRIABLE OF
RIGHT TO A JURY IN THIS ACTION.**

Dated at Milwaukee, Wisconsin, this 11th day of May, 2012.

HABUSH HABUSH & ROTTIER S.C.
Attorneys for Plaintiffs

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